K031815

SEP 10 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

General information

Company Name	:	Philips Medical Systems Nederland BV
Address	:	Veenpluis 4-6 Best, Netherlands, 5684 PC
Registration No.	:	3003768277
Contact person	:	Lynn Harmer. Manager, regulatory Submissions Tel: (425) 487-7312 Fax: (425) 487-8666 Lynn.Harmer@Philips.com

Device (Trade) Name	:	**INTERA-SENSATION[1] family.**
Classification Name	:	Magnetic Resonance Diagnostic Device (MRDD).
Classification	:	Class II.
Product code	:	LNH
Performance standards	:	NEMA voluntary standards, FDA MR Diagnostic Device Guidance, UL and IEC 601 appropriate safety standards and/or draft standards are used

Predicate Device(s):

The Philips Medical Systems **INTERA-SENSATION Family Release 1-series** is the successor of the already cleared (predicate device) Gyroscan INTERA family release 10-series with static magnetic field strengths of 1.0, 1.5 and 3.0 Tesla.

Indications for use:

The **INTERA-SENSATION Family Release 1-series** magnetic resonance diagnostic devices produce transverse, sagittal, coronal and oblique cross-sectional images based upon ^{1}H metabolites, and that displays the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis

[1] This is not the final system name and will change. At the moment of this writing the system name is not known yet.

Device description:

The INTERA-SENSATION Release 1 family is the successor of the current (Gyroscan) INTERA family Release 10-series. It consists of various configurations with magnetic field strengths (1.0T, 1.5T & 3.0T) and different optional gradient types.

The INTERA-SENSATION Release 1 family is based on the same platform with the same functionalities as its predecessor.
The main differences with the its predecessors (/ predicate devices) are:

- new appearance (covers)
- data acquisition system supports 1,4,6,8 and 16 channels and is prepared for 32 channels
- Advanced shimming and SUPER QUASAR gradient.
- Added new functionality: Examcards, MobiFlex, MobiView, Q-flow, Real Time Bold Imaging, Re-scan, and CareTrak
- Enhancements related to the use of up to date computer technology such as larger electronic data storage (memory) capacity.

General Safety and Effectiveness.

The INTERA SENSATION Release 1-series family does not induce any other risks than already indicated for the predicate devices.
.It has the same safety and effectiveness as its predecessor.

Substantial Equivalence.

It is the opinion of Philips Medical Systems that the Philips **INTERA SENSATION Release 1-series family** is substantially equivalent to its predecessor.

End

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2003

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

Re: K031815
Trade/Device Name: INTERA SENSATION[1]
Release 1 Family
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: June 5, 2003
Received: June 12, 2003

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031815

Device Name : **INTERA SENSATION[1] Release 1 family.**

Indication For Use :

The indication for use for the INTERA SENSATION Release 1-series remains the same as the previous released predicate device(s), i.e. the capability as a diagnostic device that produces transverse, sagittal, coronal and oblique cross-sectional images based upon ^{1}H metabolites, and that displays the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031815

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